K 110574 (1/2)

BIOMET MICROFIXATION

MAY 18 2011

510(k) Summary

Contact: Biomet Microfixation
1520 Tradeport Drive
Jacksonville, FL 32218-2480

Sheryl Malmberg, Global RA Specialist
904-741-9465 fax 904-741-9425

Device Name: SternaLock Blu Biomet Microfixation Sternal Closure System

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Device Product Code: 87HRS (21 CFR 888.3030) **Device Classification:** Class II

Intended Use: SternaLock Blu Biomet Microfixation Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including Sternal fixation following Sternotomy and Sternal reconstructive surgical procedures.

Description: Biomet Microfixation SternaLock Blu Sternal Closure System contains plates and 2.4mm and 2.7mm diameter self-drilling screw with maximum length of 20mm. The tip of the screw is designed so that a predrilled hole is not required, but may be used.

Material: Titanium

Sterility Information: The SternaLock Blu Biomet Microfixation Sternal Closure System will be marketed as non-sterile, single use devices. Validated steam sterilization recommendations are included in the package insert.

Possible risks:

1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
2. Nonunion or delayed union, which may lead to breakage of the implant.
3. Migration, bending, fracture or loosening of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Increased fibrous tissue response around the fracture site and/or the implant.
8. Necrosis of bone.
9. Inadequate healing.
10. Selection of screws which are longer than the depth of the sternum may cause possible impingement on structures internal to the chest wall including vessels, pleura and other structures.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

Substantial Equivalence

Characteristic	New Device	Predicate	
Design	The SternaLock Blu Closure System includes screws with longer lengths that lock into system plates to stabilize and fixate fractures of the anterior chest wall.	K011076 K033740 K063506	
Material	Plates: TI Grade IV Screws: TI-6AL-4V	K011076 K033740 K063506	
Size Range	Plates: various configurations Screws: 8mm to 20mm length	K011076 K033740 K063506	
Test	**Requirement**	**New Device**	**Predicate Device**
Torsional insertion and fracture test	Meet or exceed parameters of predicates.	Exceeded Requirements	K011076 K033740 K063506
Conclusion:	**No clinical testing was necessary for a determination of substantial equivalence. The results of mechanical testing indicated the devices performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate device.**		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomet Microfixation
% Ms. Sheryl Malmberg
Global Regulatory Affairs Specialist
1520 Tradeport Drive
Jacksonsville, Florida 32218

MAY 18 2011

Re: K110574
Trade/Device Name: Biomet Microfixation SternaLock Blue Sternal Closure System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: April 20, 2011
Received: April 21, 2011

Dear Ms. Malmberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K110574

Device Name: Biomet Microfixation SternaLock Blu Sternal Closure System

Indications for Use:

Biomet Microfixation SternaLock Blu Sternal Closure System is intended for use in the stabilization and fixation of fractures of the anterior chest wall including Sternal fixation following Sternotomy and Sternal reconstructive surgical procedures

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110574